

REMARKS

The rejection of claims 3, 6-7 and 12, under 35 USC 112, first paragraph, as failing to comply with the written description requirement, are respectfully traversed.

Applicant has amended claim 3 to delete the word "relatively" and the words "and shape" but leaving the term "uniform size" which is supported throughout the specification, such as on page 21, lines 23-28 and more particularly on page 24, lines 13-18. In addition, page 34, lines 3-5, specifically states that "the present multi-layer liposomes prepared in test examples 1-3 all maintained their size in a relatively uniform range" which also clearly supports claim 3, as amended. Accordingly, the rejection of claim 3, under 35 USC 112, first paragraph, should be withdrawn.

Claim 7 has been canceled.

Claims 6 and 12 depend from claim 3, which has been amended to overcome the rejection under 35 USC 112 and accordingly the rejection of claims 6 and 12 should also be withdrawn.

The rejection of claims 3, 6 and 12 under 35 USC 103(a) as being unpatentable over Popp '657 in combination with Foldvari '755 and optionally in further combination with Needham '298 is respectfully traversed.

Applicant has attached hereto an executed Declaration under 37 CFR 1.132, which is directed to the allegation of the Examiner that "although Popp does not teach using a fatty acid, it teaches an oil" which the Examiner alleges is essentially a fatty acid

and that therefore, Popp must be “implicitly” producing multilayered liposomes.

The Declaration under 37 CFR 1.132 is executed by the inventor Deekhoon Park, who holds a PhD in this field and is the author or co-author of many articles in this field. In addition, the Declarant has been granted multiple patents related to multilayered liposome compositions and methods of preparation, all of which are identified in the Declaration.

As set forth in paragraph 5, on page 8 of the Declaration based on the results shown in the Declaration the Declarant concludes that “it is proven that a multilayered liposome cannot be prepared by the method according to Example 1 of Popp, without using a high-pressure homogenizer”. The Declarant further states that “in addition, it is also proven that the multilayered liposome cannot be prepared by a method which uses the oil components disclosed in Popp....according to Example 1 of Popp using a non-high-pressure homogenizer”.

In contrast, multilayered liposomes, highly uniform in size, based on the claimed narrow range, are being claimed using the method of claim 3 which requires the agitation step to be carried out without use of a high-pressure homogenizer. Accordingly, the allegation of the Examiner in paragraph 4 on page 3 of the office action that “since the method of preparation (in Popp) is the same, the presence of multilayered liposomes is implicit” is without foundation and is an inaccurate statement. The method of preparation is not the same as the method of claim 3, which requires multilayered liposomes to be formed of uniform size within a very narrow particle size

range of between 800-1000 nm and with the oil-phase components including fatty acids in an amount of from 0.1 to 20wt. % and further specifically requiring the agitation step to be carried out without the use of a high-pressure homogenizer. None of these limitations are present in Popp. To the contrary, a high-pressure homogenizer is, in fact, implicit in the method of Example 1 taught in Popp to form multilayered liposomes. This is substantiated in the executed Declaration, which proves that a multilayered liposome cannot be prepared by the method according to Example 1 of Popp without using a high-pressure homogenizer. The Declaration also proves that multilayered liposomes cannot be formed based on using oil components in the absence of fatty acids if a non-high-pressure homogenizer is used. Accordingly, the statement of the Examiner that "the presence of multilayered liposomes is implicit" is without foundation, unsupported and erroneous, unless Popp is carrying out the agitation step using a high-pressure homogenizer. Multilayered liposomes are either not being formed using the method taught by Popp as proven by applicant or are being formed by using a high-pressure homogenizer.

Moreover, the presence of both fatty acids and squalene are critical to the method of the subject invention for forming multilayered liposome which will remain stable and uniform in size within the claimed narrow size range of 800-1000 nm. The Examiner admits that the secondary reference Foldvari lacks the teaching of squalene and lacks the teaching of forming multilayer liposomes in the claimed size range.

Moreover, the Examiner makes no attempt to show why it would be obvious to

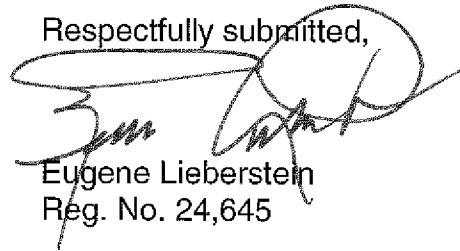
one skilled in the art, from the teaching of Foldvari, to use squalene or to add a fatty acid to Popp to form multilayered liposomes without the use of a high-pressure homogenizer which is implicit in Example 1 of Popp.

For all of the above reasons, claim 3 and its dependent claims 6 and 12 are clearly patentable over Popp in view of Foldvari, alone or in combination with Needham. The Examiner's allegation regarding the criticality of sizes has no relevance to the control of the speed of the mechanical vibration or homogenization and is without foundation. There is simply nothing in the prior art cited in Popp or Foldvari for the Examiner to conclude that one of ordinary skill in the art would expect the sizes of the liposomes to be uniform within the claimed narrow size range when applicant has already established in the attached Declaration that the presence of multilayered liposomes in Popp is implicitly using a high-pressure homogenizer or that multilayer liposomes are not being formed. Since Popp does not teach how to form multilayered liposomes, all that can be implied by one skilled in the art is that multilayer liposomes will be formed in Popp provided a high-pressure homogenizer is used since the example taught in Popp implicitly requires a high-pressure homogenizer to form multilayer liposomes or none will be formed.

For all of the above reasons, claim 3 and its dependent claims 6 and 12 are clearly patentable over Popp taken in combination with Folvari or further in combination with Needham for all of the reasons given above.

Reconsideration and allowance of claims 3 and 6 and 12 is respectfully solicited.

Respectfully submitted,



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CERTIFICATE OF TRANSMISSION

I hereby certify that this Amendment is being submitted to the USPTO via EFS-Web addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450, on September 13, 2011.

By 
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